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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/557,423 04/21/00 BELOTSEKOVSKII

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027310 HM22/1003
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EXAMINER

LOEB, R

ART UNIT

PAPER NUMBER

1636

DATE MAILED:

10/03/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/557,423

Applicant(s)

BELOTSEKOVSKII ET AL.

Examiner

Bronwen M. Loeb

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 July 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5,7-26,28-47,49-66,108 and 112 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5,7-26,29-47,50-66,108 and 112 is/are rejected.
- 7) ☒ Claim(s) 28 and 49 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 April 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) Z.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

This action is in response to the amendment filed July 23, 2001 in which claims 6, 27 and 48 were cancelled and claims 1-11, 14, 21-26, 28-35, 39, 42-47, 49-53, 60, 63, 64, 108 and 112 were amended.

Any rejections in any previous action not repeated herein have been withdrawn.

Claims 1-5, 7-26, 28-47, 49-66, 108 and 112 are pending.

Sequence Compliance

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 because **the computer readable format (CRF) and the sequence listing both filed July 23, 2001 do not have the same number of sequences and are therefore clearly not identical**. If the Sequence Listing required for the instant application is identical to that of another application, a letter may be submitted requesting transfer of the previously filed sequence information to the instant application. For a sample letter requesting transfer of sequence information, refer to MPEP § 2422.05. Additionally, it is often convenient to identify sequences in figures by amending the Brief Description of the Drawings section (see MPEP § 2422.02).

Applicants are required to comply with all of the requirements of 37 CFR 1.821 through 1.825. Any response to this office action that fails to meet all of these requirements will be considered non-responsive. The nature of the noncompliance with the requirements of 37 C.F.R. 1.821 through 1.825 did not preclude the continued examination of the application on the merits, the results of which are communicated below.

Response to Amendment

Claims 18-21, 39-42 and 60-63 stand rejected under 35 USC §112, second paragraph for the reasons of record and as further discussed below.

Art Unit: 1636

Claims 1, 8, 9-21, 22, 29-42, 43, 50-66 and 108 stand rejected under 35 U.S.C. 102(e) as being anticipated by Pati et al (USP 5,948,653).

Claims 1, 7, 12-14, 18-22, 30, 33-35, 39-42 stand rejected under 35 U.S.C. 102(b) as being anticipated by Sena et al (USP 5,273,881).

Claim 112 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Pati et al.

Claims 1-3, 8, 9-21, 22-24, 29-42, 43-45, 50-66 and 108 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Pati et al as applied to claims 1, 8, 9-21, 22, 29-42, 43, 50-66 and 108 above, and further in view of Helene et al (Biochimica et Biophysica Acta (1990) 1049:99-125).

Claims 1, 5, 7, 8, 9-21, 22, 26, 28-42, 43, 48-66 and 108 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Pati et al as applied to claims 1, 8, 9-21, 22, 29-42, 43, 50-66 and 108 above, and further in view of Barton (USP 5,225,556).

Claims 1, 4, 8, 9-21, 22, 25, 29-42, 43, 46, 50-66 and 108 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Pati et al as applied to claim claims 1, 8, 9-21, 22, 29-42, 43, 50-66 and 108 above, and further in view of Simonsson et al (Nucleic Acids Research (1998) 26:1167-1172).

Response to Arguments

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 1636

2. Claims 18-21, 39-42 and 60-63 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant's arguments filed July 23, 2001 have been fully considered but they are not persuasive. Applicants state that they have amended claims 18, 39 and 60 to overcome the rejection however no such amendments have been submitted. Therefore, the rejection is maintained.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

4. Claims 1, 8, 9-21, 22, 29-42, 43, 50-66 and 108 remain rejected under 35 U.S.C. 102(e) as being anticipated by Pati et al (USP 5,948,653).

Applicant's arguments filed July 23, 2001 have been fully considered but they are not persuasive. Applicants argue that disclosed locking sequences are capable of forming secondary structure and form non-Watson-Crick complexes such as triplexes, Z-DNA anchors or quadruplexes and that Pati et al do not disclose such locking sequences. This argument is not persuasive because Watson-Crick base pairs, also

Art Unit: 1636

known as B-DNA, are a type of secondary structure, in fact, the most common form. More importantly, the specification does not exclude Watson-Crick complexes in the definition of locking sequences. See p. 19, lines 23-26, p. 20, lines 29-31, p. 21, line 34- p. 22, line 5 and Figures 2B and 5. Indeed, in Figures 12B, far right hand set of data, and Figure 13, center box, the locking sequences of Pati et al are shown to be stabilizing of the double D-loop. The pending claim language therefore encompasses locking sequences made of Watson-Crick base pairs, such as those clearly taught by Pati et al. Therefore, the rejection is maintained.

5. Claims 1, 7, 12-14, 18-22, 30, 33-35, 39-42 remain rejected under 35 U.S.C. 102(b) as being anticipated by Sena et al (USP 5,273,881).

Applicant's arguments filed July 23, 2001 have been fully considered but they are not persuasive. Applicants argue that Sena et al does not anticipate the claims because Sena et al do not teach heterology between the probes or between the probes and the target sequence. This assertion is not entirely correct. See Sena et al, Fig. 9G which illustrates heterology between the probes and the target sequence and col. 13, lines 29-31. In Fig. 9G, the heterologous portions of the probes in fact are shown to anneal to each other, forming secondary structure, which presumably stabilizes the double D-loop. The pending claim language read on such structures and therefore are anticipated by them. The rejection is maintained.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claim 112 remains rejected under 35 U.S.C. 103(a) as being unpatentable over Pati et al.

8. Claims 1-3, 8, 9-21, 22-24, 29-42, 43-45, 50-66 and 108 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Pati et al as applied to claims 1, 8, 9-21, 22, 29-42, 43, 50-66 and 108 above, and further in view of Helene et al (Biochimica et Biophysica Acta (1990) 1049:99-125).

9. Claims 1, 5, 7, 8, 9-21, 22, 26, 28-42, 43, 47, 49-66 and 108 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Pati et al as applied to claims 1, 8, 9-21, 22, 29-42, 43, 50-66 and 108 above, and further in view of Barton (USP 5,225,556).

10. Claims 1, 4, 8, 9-21, 22, 25, 29-42, 43, 46, 50-66 and 108 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Pati et al as applied to claim claims 1, 8, 9-21, 22, 29-42, 43, 50-66 and 108 above, and further in view of Simonsson et al (Nucleic Acids Research (1998) 26:1167-1172).

Applicant's arguments filed July 23, 2001 have been fully considered but they are not persuasive. For all of the rejections under 35 USC §103, Applicants have

essentially argued that since Pati et al fail to teach or suggest every limitation of the independent claims, and none of the secondary references make up for the alleged deficiencies of Pati et al, the rejections under 35 USC §103(a) should be withdrawn. As discussed above, Pati et al is not deficient. Therefore, Applicants argument is not persuasive and the rejections are maintained.

Conclusion

Claims 1-5, 7-26, 29-47, 50-66, 108 and 112 are rejected. Claims 28 and 49 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Art Unit: 1636

Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014. NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bronwen M. Loeb whose telephone number is (703) 605-1197. The examiner can normally be reached on Monday through Friday, from 10:00 AM to 6:30 PM. A phone message left at this number will be responded to as soon as possible (usually no later than the next business day after receipt by the examiner).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, can be reached on (703) 308-0447.

Any inquiry of a general nature or relating to the status of this application should be directed to Dianiece Jacobs, Patent Analyst whose telephone number is (703) 305-3388.

Bronwen M. Loeb, Ph.D.
Patent Examiner
Art Unit 1636

September 28, 2001


ROBERT A. SCHWARTZMAN
PRIMARY EXAMINER